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(21) International Application Number: <b>PCT/US98/09977</b> (22) International Filing Date: 15 May 1998 (15.05.98) (30) Priority Data: 60/046,746 16 May 1997 (16.05.97) <b>US</b> (71)(72) Applicants and Inventors: <b>FARRELL, Peter, Craig</b> [AU/US]; 12475 Rue Fountainbleau, San Diego, CA 92131 (US). <b>PACE, Gary, William</b> [US/US]; 6913 Hunters Way, Raleigh, NC 27615 (US). (74) Agents: <b>SORENSEN, Andrew, D. et al.; Holland &amp; Hart</b> L.L.P., Suite 3200, 555 17th Street, P.O. Box 8749, Denver, CO 80201-8749 (US).		(81) Designated States: <b>AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, GW, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).</b>  <b>Published</b> <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>	
(54) Title: <b>NASAL VENTILATION AS A TREATMENT FOR STROKE</b>			
(57) Abstract  A new treatment and apparatus for acute and chronic treatment is described here which incorporates nasal ventilation, with or without concomitant drug therapy, using continuous positive airway pressure (CPAP) or bi-level pressure treatment or variants thereof, including devices which automatically set their pressures based on physiologic data inputs.			

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## NASAL VENTILATION AS A TREATMENT FOR STROKE

### FIELD OF THE INVENTION

The present invention relates to a method of treatment and apparatus for stroke patients.

### 5 BACKGROUND OF THE INVENTION

Stroke, or brain attack as it is commonly called, can be caused by either vascular hemorrhage or vascular blockage with the latter accounting for about 80% of the events which lead to a stroke. Stroke is associated with considerable morbidity in terms of long-term  
10 neurological deficit and the risk of subsequent stroke as well as mortality post stroke is considerable in stroke patients. Treatment in the acute phase typically entails the invasive administration of clot dissolving drugs within the first three hours of the stroke as well as stabilization of cardiovascular function and vital signs. Post stroke  
15 therapy can include intensive and costly rehabilitation depending on the degree of neurological deficit.

Continuous positive airway pressure (hereinafter CPAP) has been identified as a method of treatment for sleep disorders, and in particular, sleep apnea. The application of CPAP for sleep disorders  
20 was first introduced in U.S. Patent No. 4,944,310. This patent described the application of continuous positive airway pressure being applied to the patient, through the patient's nares, to treat sleep disorders, including obstructive sleep apnea. It has been found that the application of pressure which exceeds atmospheric pressure,  
25 typically 4 to 15 centimeters of H<sub>2</sub>O is useful in treating sleep

disorders. However, prior to this invention, the application of CPAP as a method for treating stroke patients has never been known.

There exists a need for a method of treatment for stroke patients which is non-invasive, and does not include the use of drugs.

5 There also exists a need for the treatment of stroke patients which is inexpensive and does not require a medical facility or hospital.

## **SUMMARY OF THE INVENTION**

A new treatment and apparatus for acute and chronic treatment of stroke patients is described here which incorporates nasal  
10 ventilation, with or without concomitant drug therapy, using continuous positive airway pressure (CPAP) or bi-level pressure treatment or variants thereof, including devices which automatically set their pressures based on physiologic data inputs.

## **DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT**

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Nasal CPAP treatment has been traditionally used for the management of patients with obstructive sleep apnea where CPAP acts as a pneumatic splint to maintain upper airway patency and therefore ensures free flow of air while the patient sleeps. The current invention  
20 describes the use of positive pressure ventilation, which may include CPAP, bi-level pressure, or variants thereof, for stroke patients. The use of CPAP treats stroke patients by improving arterial blood oxygen levels and reducing arterial carbon dioxide levels as well as improving auto-regulation of, for example, blood pressure, cardiac output and  
25 ventilation. Improvements in morbidity, such as rate and degree of recovery of vital signs and patient stabilization in the acute phase, is

an expected benefit. Also, an improvement in neurological deficits in the short and/or long term is an expected benefit.

It is understood that while the invention has been described above in conjunction with the preferred method and preferred  
5 embodiment, the description and examples are intended to illustrate but not limit the scope of the invention, which is defined by the scope of the following claims.

We claim:

1. A method for the treatment of a patient who has suffered a stroke, said method comprising the application of continuous positive airway pressure to said patient.

2. The method of claim 1 wherein said pressure is applied in a bi-level fashion.

3. The method of claim 1 wherein said patient's arterial blood oxygen level is improved.

4. The method of claim 1 wherein said patient's carbon dioxide blood level is reduced.

5. The method of claim 1 wherein auto regulation of blood pressure, cardiac output and ventilation is improved.

6. An apparatus for the treatment of stroke patients, said apparatus comprising:

(a) an airflow generator;

(b) an interface adapted to fit a patient; and

5 (c) a conduit for the flow of air from said generator to said interface, said airflow being delivered to said interface at a pressure which exceeds atmospheric pressure for at least a portion of a breathing cycle of said patient.

## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US98/09977

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61M 16/00; A62B 7/00; F16K-31/02

US CL :128/204.18, 204.23

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/200.24, 204.18, 204.23, 205.25, 207.18

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

APS: CPAP, BI-PAP, BI(W)LEVEL- CPAP

Search Terms: stroke, ventilat?, respirat?

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,590,648 A (MITCHELL ET AL) 07 January 1997, col. 1 lines 58-67; col. 2 lines 1-28; col. 3 line 1 to col. 5 line 3, and col. 8 lines 6-13.	1-6

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

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